REMARKS

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-40 are pending in the present case. In the Final Office Action dated November 12, 2010, the Examiner maintained rejection of Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 under 35 U.S.C. §103, as allegedly being unpatentable over Lapidus, *et al.*, (US 6,143,529; 11/7/00) in view of Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5).

Applicants disagree with the maintained rejections for the reasons made of record in the responses filed on June 1, 2010 and October 18, 2010, which are incorporated here by reference. However, for business reasons and without acquiescing to the Examiner's arguments, and reserving the right to prosecute the original or similar claims in one or more future applications, Claims 1, 14, and 24 are amended to recite that nucleic acid fragments are amplified from "unfractionated heterogeneous DNA isolated from a stool sample." The remaining claims under examination depend from Claim 1, 14, or 24, and thus also comprise this feature. Support for this amendment is found, *e.g.*, in Example 1, which describes the isolation of unfractionated DNA from stool samples in paragraph [0059], and describes PCR amplification from this total DNA in paragraph [0060].

As noted in the Amendment and Response filed on October 18, 2010, incorporated here by reference, Lapidus does not teach or suggest analysis of DNA fragments amplified directly from unfractionated heterogeneous DNA comprising material other than human DNA. Rather, as discussed in the Response of October 18, 2010 at page 8, Lapidus particularly emphasizes the difficulty of detecting cancer indicia in the heterogeneous environment of a stool sample. Thus, Lapidus teaches that, prior to amplification, the human DNA to be amplified is purified by fractionation from the heterogeneous population of molecules by sequence-specific hybrid capture prior to the amplification step. See, *e.g.*, col 10 lines 29-30. Lapidus does not disclose amplification directly from unfractionated heterogeneous DNA isolated from a stool sample.

The Examiner has asserted that that the deficiency in Lapidus with respect to measurement of genome equivalents is made up in the teachings of Hromadnikova *et al.* (Office Action, page 5). While Hromadnikova does teach determination of "genome

equivalents", the teachings of Hromadnikova are not sufficient to make up for all of the deficiencies of Lapidus discussed above. Hromadnikova fails to teach or suggest a method comprising the step of amplifying from the unfractionated heterogeneous DNA isolated from a stool sample, the stool sample comprising DNA from shed cells and shed cellular debris." As such, even if the teachings of Hromadnikova are combined with the teachings of Lapidus (Applicants do not concede that such a combination is proper or would be made by one of skill in the art), the combination fails to teach or suggest each and every feature of the instant claims.

It remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. Section 2143.03 of the MPEP, citing *See In re Wada and Murphy*, *citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). While Applicants do not acquiesce that the other elements necessary for establishing prima facie obviousness have been met, Applicants submit that the combination of Lapidus and Hromadnikova does not teach or suggest all the features of Claims 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-40, and cited art therefore fails to establish prima facie obviousness. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and Applicants' claims should be passed to allowance. If the Examiner wishes to discuss this case, Applicants encourage the Examiner to call the undersigned at 608-662-1277 at the Examiner's convenience.

Dated: January 11, 2011

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